

REMARKS

The above-reference Office Action has been carefully reviewed and reconsideration thereof is respectfully requested.

Claims 1-4 have been rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. Applicant respectfully traverses this ground of rejection in view of the amendments previously filed.

Does the Examiner have copies of the Amendment mailed December 21, 2001, the Supplemental Preliminary Amendment mailed January 24, 2001, and the Preliminary Amendment mailed November 27, 2000? If so, the Examiner should find support for the claims in the documents mailed.

Claims 1-4 have been rejected under 35 USC 112, second paragraph, as being indefinite and confusing. Applicant respectfully traverses this ground of rejection.

The animal or human may have more than one type of tumor.

Claims 1-4 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-4 of US Patent No. 5,692,478. Applicant respectfully traverses this ground of rejection.

There is absolutely nothing suggesting or clarifying an anti-tumor effect by the pyridones cited in the patent. There is absolutely nothing in the patent that describes any anti-tumor action for any of the pyridones. The only thing that is mentioned anywhere in the entire document is the fact that certain tumors can cause a release of significant amounts of TNF- $\alpha$ , and that the action of the TNF- $\alpha$  could be inhibited by the pyridones.

In the claims section, absolutely nothing is stated suggesting or claiming any anti-tumor growth action for any for pirfenidone or any of the pyridone molecules.

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There is nothing in the cited patent that says that pyridone substances can be used to treat neoplastic disease. The only thing cited for the pyridones under the patent is the inhibiting action of the compounds on the effects of the TNF- $\alpha$  cytokine. TNF- $\alpha$  is not the cause of the onset or continued growth of neoplastic diseases. There is absolutely no suggestion, hint, or speculative representation in the patent that the cited pyridones would have an inhibitory effect on the proliferative growth of tumors.

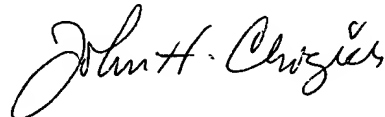
The amendments to the Specification and to Claims 1 and 4 clarify some of the language. It is respectfully submitted that those amendments are obvious from the context.

In view of the above amendments and remarks, it is respectfully submitted that the claims in the application, Claims 1-4, are allowable and early action in that regard is respectfully requested.

Should the Examiner have any questions as to the allowability of the claims or any suggestions with respect thereto, the undersigned would be grateful for the privilege of a telephone conference with the Examiner.

Date: April 28, 2005.

Respectfully submitted,



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AMENDMENTS TO THE DRAWINGS

None.